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510k Summary

510k Summary for the TL10 Tensymeter Non-invasive Blood Pressure Monitor

Submitter:

Tensys Medical, Inc.
5825 Oberlin Drive Suite 100
San Diego, CA 92121
Phone 858-552-1941
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Contact:

Stuart L. Gallant, President

Date prepared:

Trade Name:

TL10 Tensymeter **Non-invasive** Blood Pressure Monitor

Common name:

Non-invasive blood pressure measurement system.

Classification:

Class II per 21 CFR 870.1130
Non-invasive blood pressure measurement system.

Predicate Device:

Tensys Medical, Inc. believes that the TL10 Tensymeter is substantially equivalent to the Colin Medical Instruments Corp.CBM-7000 Blood Pressure System (K900247)

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Device Description:

The TL10 Tensymeter is a non-invasive blood pressure monitor that utilizes a single patient use non-invasive pressure sensor placed on the wrist, over the radial artery, and an electronic interface module. The device uses proprietary algorithms to analyze the radial artery pressure and display diastolic, systolic, mean blood pressure, pulse rate and a pressure waveform.

Intended Use:

This device is intended for use by medically trained personnel in a clinical setting to continuously monitor and display diastolic, systolic, and mean blood pressures. The device is intended for use on adult patients with a palpable pulse.

Comparison of Technological Characteristics of New Device to Predicate Device(s):

The design of the TL10 Tensymeter utilizes a semiconductor pressure-sensing element applied to the wrist, over the radial artery, to obtain a pressure waveform in the same manner as the predicate device.

Clinical Tests:

Clinical test were performed which show test results which meet or exceed the accuracy requirements of AAMI Standard SP-10 -1992

Non-Clinical Tests:

Patient Contact Materials
ISO 10993-1

Electrical Safety
IEC 60601-1

Electromagnetic Compatibility

IEC 60601-1-2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2002

Tensys Medical, Inc.
c/o Mr. Stuart L. Gallant
President and Chief Operating Officer
5825 Oberlin Drive, Suite 100
San Diego, CA 92121

Re: K020537
Trade Name: TL10 Tensymeter Blood Pressure Monitoring System
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: June 6, 2002
Received: June 7, 2002

Dear Mr. Gallant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K020537

Device Name: TL10 Tensymeter Blood Pressure Monitoring System

Indications for Use:

This device is intended for use by medically trained personnel in a clinical setting to continually monitor and display diastolic, systolic, and mean blood pressures and pulse rate. The device is intended for use on adult patients with a palpable pulse.

Prescription Use Yes
(Per 21 CFR 801.109)

(Division Sign-Off) 8/14/02
Division of Cardiovascular
and Respiratory Devices
510(k) Number K020537